REMARKS

A Request for Continued Examination is concurrently filed with the present amendment, as the amendment to the claims is expected to require further search and/or consideration.

The amendment is intended to place the application in condition for allowance.

Status of the Claims

Claims 1 and 5 are amended.

Claim 1 now identifies the chemical species as being fatty acids and derivatives thereof, e.g., as previously recited in claim 5 and described in the specification at, for example, [0038] and Example 2 in [0079].

Claims 1-5, 7-11, 15, 17-25 remain in this application.

Claims 2-5, 7-11, 15, 19-25 stand withdrawn.

Claim Rejections-35 USC §103

Claims 1 and 17-18 stand rejected under 35 U.S.C. § 103(a) as being obvious over KUMAR Journal of Pharmacy and Pharmaceutical Sciences 2000 3: 234-258 ("KUMAR") in view of KELLER US 6,726,924 ("KELLER") and BAKER et al. US 6,534,018 ("BAKER"). This rejection is respectfully traversed for the reasons below.

The claimed invention is directed to a vector for the oral administration of at least one pharmacologically

active substance. The vector includes a matrix, which is essentially hydrophilic in nature and has an outer surface modified with one or more fatty acids and/or their derivatives attached to the matrix by weak bonds. The weak bonds are capable of detaching the fatty acids and/or their derivatives from the matrix upon contact with microvilli present in the intestine. At least one pharmacologically active substance being contained within said matrix.

KUMAR discloses crosslinked chitosan microspheres coated with a DPPC lipid multilayer for delivering 5-FU (See, e.g., page 247, Figure 10). These microspheres comprise a chitosan matrix containing 5-FU, and the outer surface of each microsphere is modified with the DPPC lipid multilayer.

However, KUMAR fails to disclose the detachment of the DPPC lipid multilayer from the chitosan matrix. On the contrary, as mentioned above, the DPPC lipid multilayer for delivering 5-FU, i.e., the multilayer is effective for preventing the release of 5-FU (e.g., page 248, Column 1, paragraph 1).

Thus, KUMAR does not teach that upon contact with microvilli present in the intestine during passage through the intestinal lumen, the fatty acid multilayers detach from the chitosan matrix such that the matrix becomes essentially hydrophilic in nature.

Accordingly, contrary to the position presented in the Official Action, it would not have been “obvious to try” to even

approach, as the skilled person would have an indefinite number of solutions to modify KUMAR so as to prepare a vector exhibiting the above described property. The Official Action presents no finding of facts with respect to (1) selection of fatty acids or their derivatives, (2) weak bonds between a hydrophilic core and lipophilic fatty acids or their derivatives such that the fatty acids or their derivatives detach upon contact with microvilli present in the intestine.

That is, the choice of fatty acids as a chemical species for the matrix modification was not obvious over KUMAR, as there was no finite number of identified predictable solutions to the recognized need, and no reasonable expectation of success. One could have chosen any lipophilic chemical species to modify the matrix.

As established by *Takeda Chemical Industries Ltd v. Alphapharm Pty. Ltd* (492 F3d 1350 Fed. Cir. 2007: "The obvious to try rationale does not apply when there was no finite number of identified predictable solutions to the recognized need, and no reasonable expectation of success."

In the present case, the skilled person would have to select the fatty acids within a large choice of usual lipophilic chemical species. There is no reason in KUMAR that would have led one to select these chemical species and there would have been no expectation of success.

Thus, the reliance on KUMAR for teaching or suggesting such features is improper.

Neither KELLER nor BAKER is able to remedy these deficiencies of KUMAR for reference purposes. KELLER teaches a drug containing particulate lipophilic vector included with a liquid carrier in a gelatin capsule, which is coated with an enteric polymeric coating, and BAKER teaches a drug containing a particulate lipophilic composition that is to be delivered with a glycol-type or oil-type carrier. Neither of these documents mentions or suggests the modification by fatty acids of the outer surface of a hydrophilic matrix containing an active substance.

Therefore, the proposed combination fails to teach or suggest the claimed invention.

The proposed combination also fails to suggest (or express a need for) the unexpected properties achieved by the claimed invention. It is the choice of fatty acids (or their derivatives) as chemical species for the matrix modification that leads to unexpected results. The choice of the fatty acids enables the vector to be stable and protected through the gastro intestinal tract, but allow the vector to be adsorbed onto and across the intestinal wall.

That is, this modification with fatty acids enables the formation of a vector allowing the active substance to avoid degradation and denaturing during the passage across the intestinal wall.

Therefore, the proposed combination fails to render obvious the claimed invention, and withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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